actually intended to affect the structure or function of the body, it is not necessary for the Agency to show that consumers use tobacco nearly exclusively for its pharmacological effects. Some courts have suggested such a showing could be required, but only where there is no other evidence of the intended use and FDA is relying exclusively on actual consumer use. *Action on Smoking and Health v. Harris,* 655 F.2d 236, 240 (D.C. Cir. 1980). The "nearly exclusive" consumer use standard is inapplicable in the context of direct evidence of manufacturers intent. *See* sections II.B.1., above, and II.E.1., below.

3. In the Jurisdictional Analysis, 60 FR 41601, FDA stated that attorneys for RJR had, in a court filing, described the following pharmacological "benefits" of smoking: "satisfaction; stress reduction; relaxation; stimulation; aided concentration; increased memory retention; alleviation of boredom and fatigue; avoidance of loss of vigilance in repetitive and sustained tasks."[873] RJR argues that FDA's use of this litigation response was misleading because: (1) the listed benefits were only those reported by smokers or the literature, and were not subscribed to by RJR; (2) FDA omitted from the quote benefits that were not pharmacological; and (3) the listed benefits were not characterized by RJR as "pharmacological" or "significant," and are likely due to other aspects of smoking, including the sensory aspects. RJR also states that even if some of the benefits quoted by FDA "are in some sense pharmacological," the litigation response is not evidence of intended use.

[873] Reply to Interrogatories, *Gilboy v. American Tobacco Co. et al.*, No. 314002 (La. Dist. Ct.). *See* AR (Vol. 15 Ref. 194-1). FDA notes that Lorillard has not contested FDA's reliance on a similar court filing by Lorillard in *Covert v. Lorillard et al.*, No. 88-1018-B (M.D.La). *See* AR (Vol. 15 Ref. 194-2).

II.C.6.

FDA disagrees that its use of the company's statements in litigation was misleading or that the statements fail to provide evidence of intended use. The statement filed in court by RJR was used as evidence that RJR, *speaking as a corporation*, knows that consumers use tobacco for its pharmacological effects. The knowledge of a manufacturer that its product is used for pharmacological effects provides objective evidence of intent to affect the structure and function of the body. The fact that RJR was repeating benefits reported by consumers does not in any way undercut FDA's reliance on the quote: RJR's awareness of how consumers use its product is highly relevant. The fact that the original quote included two nonpharmacological "benefits" of smoking similarly fails to diminish the relevance of the quote. When it has been established that a manufacturer intends that its product be used for a pharmacological purpose, FDA's jurisdiction is not defeated by a showing that the manufacturer also intends the product to be used for other, nonpharmacological purposes. *Guardian Chemical Corp.*, 410 F.2d at 162-163.

Finally, while RJR did not explicitly characterize the benefits as pharmacological in this particular filing, RJR scientists have published reports demonstrating that the company knows that these "benefits" of tobacco are due to the pharmacological effects of nicotine. In one paper, for example, RJR scientists reported on a study whose purpose was to isolate the psychopharmacological effects of nicotine from the effects of other aspects of the cigarette:

> Anxiety relief and improved mental alertness are two of the benefits of smoking commonly reported by smokers as their reason for smoking . . . . [The study results] indicate that *the beneficial effects*

> *of smoking on cognitive performance . . . are a function of nicotine absorbed from cigarette smoke upon inhalation.*[874]

Thus, RJR scientists characterize the very effects that the corporation listed in the pleading as nicotine's pharmacological effects.

4. RJR challenges FDA's use in the Jurisdictional Analysis of the statement of its former CEO, F. Ross Johnson, in response to a question from a reporter about whether tobacco is addictive: "Of course it's addictive. That's why you smoke the stuff."[875] RJR argues that this statement is not evidence of intent because, as Johnson "explained" in a subsequent letter to the reporter, he used the term "addictive" not in the "technical" sense, but as an expression of the "common experience that some people find it hard to quit smoking, and so continue to smoke."[876] RJR also argues that Johnson's statement should not be attributed to RJR because, at the time he made it, he was no longer employed by RJR, and "there is no indication that Johnson's comment reflected anything he learned or observed" at RJR.[877]

The arguments put forward by RJR for discounting the statement of its former CEO are not persuasive. It is doubtful that the former CEO of a tobacco company would

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[874] Robinson JH, Pritchard WS, Davis RA (R.J. Reynolds Tobacco Co.), Psychopharmacological effects of smoking a cigarette with typical "tar" and carbon monoxide yields but minimal nicotine, *Psychopharmacology* 1992;108:466-472, at 471 (emphasis added.). *See* AR (Vol. 11 Ref. 129-3).

See also Pritchard WS (R.J. Reynolds Tobacco Co.), Electroencephalographic effects of cigarette smoking, *Psychopharmacology* 1991;104:485-490 (presenting evidence that both mental alertness and anxiety reduction are a function of nicotine's effects on different parts of the brain). *See* AR (Vol. 3 Ref. 23-1).

[875] Shapiro E, Big spender finds new place to spend, *Wall Street Journal* (Oct. 6, 1994). *See* AR (Vol. 21 Ref. 230).

[876] R.J. Reynolds Tobacco Co., Comment (Jan. 2, 1996), at 21. *See* AR (Vol. 519 Ref. 103).

[877] *Id.*

state that tobacco is "addictive" without foreseeing that he would be understood to mean the term in its "technical" sense. The further suggestion that the statement did not reflect Johnson's knowledge while at RJR is similarly unconvincing.

5. RJR argues that FDA incorrectly stated that a particular research article[878] found that tobacco users report "craving." FDA has reviewed the article in question and agrees with the comment that it does not clearly find that smokers report craving.

iii. Comments on Specific Brown & Williamson Statements and Research Projects. In the Jurisdictional Analysis, FDA cited over 75 Brown & Williamson and BATCO documents to demonstrate the cigarette manufacturer's knowledge that cigarettes produce significant pharmacological effects, including causing and sustaining addiction, and are used by smokers for these effects. FDA also cited a substantial number of documents from Brown & Williamson's affiliate, Imperial Tobacco, and from American Tobacco, a company with which Brown & Williamson recently merged. Although Brown & Williamson makes a general assertion that the Agency has mischaracterized these documents, the company makes no attempt to refute FDA's specific characterizations of the vast majority of the Brown & Williamson documents cited by FDA. The Agency believes that these documents speak for themselves and fully support its conclusion that Brown & Williamson intends cigarettes to affect the structure and function of the body.

With respect to the few Brown & Williamson documents regarding nicotine pharmacology that the company does specifically address, FDA has reviewed the company's comments and concludes that the company's statements and research were

[878] Robinson JH, Pritchard W, The role of nicotine in tobacco use, *Psychopharmacology* 1992;108:395-405. *See* AR (Vol. 14 Ref. 175).

properly characterized in the Jurisdictional Analysis. These comments and FDA's responses are presented below.

1. FDA relied on a large number of statements from researchers and high-ranking officials of Brown & Williamson and BATCO acknowledging that nicotine is addictive. Brown & Williamson makes a general argument that none of the statements by BATCO employees about addiction is attributable to Brown & Williamson, because their employees were merely reciting language from government and other external sources. The company provides only one example to support this contention. FDA quoted from a speech by Charles Ellis, the science advisor to BATCO's Board of Directors, in which he told an audience of tobacco industry officials: "smoking is a habit of addiction . . . ."[879] According to the comment, Ellis' "terminology mirrored virtually identical phrases used by the Royal College of Physicians three months earlier . . . [and] does not support any conclusion about his own views."[880] Brown & Williamson also makes a baffling argument that the Surgeon General two years later determined that smoking was a "habit" rather than an "addiction" and that the Surgeon General's determination "clearly trumps the earlier imprecise language quoted by FDA."

FDA has reviewed the full text of Ellis' speech and finds no support for Brown & Williamson's contention that Ellis was merely reciting the views of the Royal College; in the quoted passage, Ellis is clearly stating his own views. FDA is similarly unable to conclude that the 1964 determination of the U.S. Surgeon General transformed Ellis' assertion two years

[879] Ellis C (BATCO), The smoking and health problem, in *Smoking and Health–Policy on Research*, Research Conference, Southampton, England (1962), at 4. *See* AR (Vol. 21 Ref. 220).

[880] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 27. *See* AR (Vol. 529 Ref. 104).

earlier that "smoking is a habit of addiction" into the statement that it is simply a habit. Because Brown & Williamson provides no evidence that other statements of its officials concerning the addictive properties of nicotine were not their own views, and the documents themselves do not support such a conclusion, FDA finds no basis to disregard those statements.

2. Brown & Williamson also challenges FDA's reliance on a report entitled, "A Tentative Hypothesis on Nicotine Addiction," arguing that it was not written by tobacco company researchers, reports no data, and is "nothing more than speculation."[881]

The report in question was sent to BATCO by the Battelle scientists who were doing contract work for BATCO on nicotine pharmacology, among other things, and contains their hypothesis of the mechanism by which smokers become addicted to nicotine. While the document hypothesizes as to the *mechanism* of addiction, it treats the existence of nicotine addiction as a fact, not hypothesis. For example, after hypothesizing that when smokers are deprived of nicotine, their endocrine systems become unbalanced, the report says: "[a] body left in this unbalanced status craves for renewed drug intake in order to restore the physiological equilibrium. This unconscious desire explains the addiction of the individual to nicotine."[882]

A copy of the report was sent by Charles Ellis to Addison Yeaman, the general counsel of Brown & Williamson. Accordingly, this document provides evidence that

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[881] *Id.* at 29.

[882] Haselbach C, Libert O, *A Tentative Hypothesis on Nicotine Addiction* (May 30, 1963), at 2. *See* AR (Vol. 20 Ref. 197-1).

company executives had knowledge that nicotine is addictive.[883] Indeed, shortly thereafter, Yeaman wrote a memo in which he accepted the view that nicotine is addictive, and concluded, "[w]e are, then, in the business of selling nicotine, an addictive drug."[884]

3. A comment from Brown & Williamson argues that FDA has distorted its nicotine research by not recognizing that the research failed to confirm the hypotheses of its researchers. In support of this argument, Brown & Williamson offers only one example. According to the comment, the results of "Project HIPPO" failed to support its hypotheses.

The example put forward by Brown & Williamson does not establish that FDA distorted Brown & Williamson nicotine research. First, Brown & Williamson fails in its attempt to show misuse of the research project. Second, FDA relied on dozens of Brown & Williamson documents reflecting over thirty years of research, the vast majority of which Brown & Williamson does not challenge.

Project HIPPO consisted of a series of studies commissioned in the early 1960's by BATCO to investigate the role of nicotine in why people smoke, and specifically to compare the effects of nicotine with those of tranquilizers, which were perceived as marketplace competition for tobacco:

> The aim of the whole research "HIPPO" was to understand some of the activities of nicotine—those activities that could explain why

[883] Letter from Ellis C to Yeaman A (Brown & Williamson) (Jun. 28, 1963). *See* AR (Vol. 14 Ref. 165-2).

[884] Yeaman A (Brown &Williamson), *Implications of Battelle Hippo I and II and the Griffith Filter* (Jul. 17, 1963), at 4. *See* AR (Vol. 21 Ref. 221). Brown & Williamson protests FDA's use of this document, claiming that it was stolen from Brown & Williamson and is privileged. FDA does not believe that this document can be considered confidential, having been published in newspapers and other media throughout the United States and made available to the public without limitation by the University of California.

> cigarette smokers are so fond of their habit. It was also our purpose to compare these effects of the new drugs called "tranquillizers" which might supersede tobacco habits in the near future.[885]

Contrary to the position taken by Brown & Williamson, Project HIPPO's authors reported that they were successful in demonstrating that nicotine was superior to tranquilizers in certain ways:

> Our investigation definitely shows that *both kinds of drugs* act quite differently, and that nicotine may be considered . . . as more "beneficial"—or less noxious—than the new tranquillizers, from some very important points of view.
>
> The so-called *"beneficial" effects of nicotine* are of two kinds:
>
> 1. Enhancing effect on the pituitary-adrenal response to stress;
> 2. Regulation of body weight." [886]

Although the researchers did not show that nicotine acted through certain hypothesized biochemical mechanisms, the documents demonstrate that this was not the central purpose of the research. Thus, Project HIPPO successfully demonstrated to BATCO that nicotine has two significant pharmacological effects on tobacco users: it acts like tranquilizers in helping them respond to stress, and it regulates body weight.

4. A comment from a public health organization pointed out a number of additional statements in BATCO and Brown & Williamson internal documents acknowledging the importance of nicotine's pharmacological effects to use of tobacco products.[887] For example, the comment provided a copy of a handwritten note by S. J. Green, the long-time director of research and a board member at BATCO, in which Green

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[885] Haselbach CH, Libert O, *Final Report on Project HIPPO II* (Mar. 1963), at 1. *See* AR (Vol. 64 Ref. 321).

[886] *Id.* at 2 (emphasis added).

[887] American Society of Addiction Medicine, Comment (Dec. 29, 1995), at 3. *See* AR (Vol. 528 Ref. 97).

says that "[t]he strong addiction to cigarette[s] removes freedom of choice from many individuals."[888] The comment also provided a copy of a 1978 BATCO document that forecast developments in technology that could be used to produce current cigarette products. The author defined "a finished smoking material" as having the following purposes: "[t]o generate smoke, taste, and pharmacological effect."[889]

FDA agrees that many of the statements to which the comment draws attention provide additional support for the determination that Brown & Williamson knows that tobacco produces pharmacological effects on consumers, including addiction, and that consumers smoke cigarettes to sustain addiction and for other pharmacological effects.

iv. Other Comments.

1. Tobacco industry comments argue that the evidence compiled by FDA of a massive industry research enterprise on nicotine pharmacology is irrelevant to the intended use of the industry's products. The comments contend that the industry conducted this research to understand and improve its products, to compare the pharmacology of new cigarettes with that of other cigarettes, to be prepared for government restrictions on tobacco products, and to respond to consumer preferences. The comments also argue that the kind of research conducted by the industry was also being done by outside researchers and reported in the public domain. Thus, according to the comments, such research need not be related to the interests of manufacturers. For these reasons,

[888] Notes of Green SJ (1978). *See* AR (Vol. 528 Ref. 97, appendix 18).

[889] Kilburn KD (BATCO), *A Technological Forecast of the Future of Tobacco Processing* (Oct. 16, 1978), at 60. *See* AR (Vol. 258 Ref. 3524).

according to the comments, the industry's research is not evidence of intent to affect the structure and function of the body.

FDA disagrees that the industry's extensive and sophisticated research into nicotine's pharmacological effects is irrelevant to the intended use of the products. This research establishes that the industry has actual knowledge that nicotine has powerful pharmacological effects and that consumers use tobacco to obtain those effects. "Objective intent" to affect the structure or function of the body may be established by a manufacturer's "knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it." 21 CFR 201.128 and 801.4.

The argument that other researchers conducted and published nicotine research similar to that conducted by the tobacco industry fails to provide an adequate basis to disregard the industry's research as evidence of intent. Although there may undoubtedly be other motives for this kind of research, the industry's own documents establishes that their motive is directly related to providing an adequate dose of nicotine the pharmacologically active ingredient in tobacco.

In its comments, Brown & Williamson even acknowledges that some of BATCO's most significant nicotine research was conducted, not because of outside pressure, but because Charles Ellis, senior scientific advisor to BATCO, believed that an alternative cigarette that provided only a nicotine aerosol could satisfy smokers and because he wanted to identify the "beneficial properties of nicotine."[890] Indeed, as described in the

[890] Brown & Williamson Tobacco Corp., Comment (Jan. 2, 1996), at 23. *See* AR (Vol. 529 Ref. 104).